UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

IN RE: LEVAQUIN PRODUCTS LIABILITY LITIGATION,	Case No.: MDL 08-1943 (JRT)
This document relates to: ALL ACTIONS	

FINAL PRETRIAL ORDER AND SUGGESTION OF REMAND

Levofloxacin is a broad-spectrum anti-infective prescription medication sold under the name Levaquin® in the United States. Levaquin is a member of a class of anti-infectives known as fluoroquinolones. It was approved by the Food and Drug Administration ("FDA") at the end of 1996 and has been indicated for the treatment of a variety of bacterial infections.

Beginning in late 2006, certain patients who had been prescribed Levaquin began filing lawsuits against Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMJPI" or "Defendants"),[1] a wholly-owned subsidiary of Johnson & Johnson, that marketed Levaquin pursuant to a licensing agreement between Daiichi Pharmaceutical Co., Ltd. of Japan and Johnson & Johnson. The Plaintiffs primarily alleged that they were injured after taking Levaquin and that Defendants failed to adequately warn physicians of the risk of tendon disorders associated with Levaquin.

[1] Levaquin was marketed by Ortho-McNeil Pharmaceuticals, Inc. ("OMP") until December 31, 2007, when the assets of OMP were transferred to OMJPI. Effective January 22, 2011, OMJPI changed its name to Janssen Pharmaceuticals, Inc. ("Janssen").

In June 2008, the Judicial Panel on Multidistrict Litigation ("JPML") transferred fifteen actions, involving alleged tendon injuries resulting from the use of Levaquin, to this Court for consolidated and coordinated pretrial proceedings. *See In re Levaquin Prods. Liability Litg.*, 560 F. Supp. 2d 1384 (J.P.M.L. 2008). The JPML found that the actions "involve common questions of fact," and that centralization in the District of Minnesota "will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation." *Id.* at 1385.

Pursuant to Rule 7.6 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, and upon review of the files in the cases now pending in MDL 1943, the Court suggests to the JPML that the cases listed in Exhibit A are ready for remand to their appropriate transferor jurisdictions. The Court finds that these cases will no longer benefit from centralized proceedings; all common discovery and other coordinated pretrial proceedings are complete, and the remaining case-specific issues are best left to the transferor courts to decide. In addition, the Court enters this Final Pretrial Order to summarize the coordinated proceedings thus far and to provide guidance to transferor courts after remand.

BACKGROUND

A. Defendants

Defendants named in the lawsuits filed in the District of Minnesota or transferred to the MDL include: Johnson & Johnson, OMP, OMPJPI, Johnson & Johnson Pharmaceutical Research & Development, LLC ("PRD"), and Janssen.

B. Representative Counsel

By agreement, Plaintiffs proposed, and the Court approved, co-lead counsel: Ronald S. Goldser, Zimmerman Reed, PLLP, Minneapolis, Minnesota and Lewis J. Saul, Lewis Saul & Associates, Portland, Maine. Defendants were initially represented by lead counsel William Robinson, LeClair Ryan, Alexandria, Virginia and John Dames, Drinker, Biddle & Reath, Chicago, Illinois. Thereafter Defendants have been represented by James B. Irwin, Irwin, Fritchie, Urquhart & Moore, LLC, New Orleans, Louisiana and Tracy J. Van Steenburgh, Nilan Johnson Lewis PA, Minneapolis, Minnesota. In addition, each side has been represented by a court-appointed liaison counsel: for Plaintiffs, Ronald S. Goldser and for Defendants, Tracy J. Van Steenburgh. The duties and responsibilities of lead and liaison counsel are delineated in Amended Pretrial Order 1 Procedural Issues. (Docket No. 977.)[2] A Second Amended Pretrial Order 1 was issued on February 23, 2011, to reflect the substitution of James Irwin, Irwin Fritchie Urquhart & Moore LLC, as co-lead counsel for Defendants in place of William Robinson. (Docket No. 2632.) A Third Amended Pretrial Order 2 was issued on May 7, 2014, to reflect the substitution of Genevieve Zimmerman, Zimmerman Reed PLLP, as co-lead and liaison counsel for Plaintiffs in place of Ronald S. Goldser. (Docket No. 6622.) Finally, a Fourth Amended Pretrial Order 1 was issued on September 10, 2014, to reflect the substitution of Charles S. Zimmerman, Zimmerman Reed PLLP, as co-lead and liaison counsel for Plaintiffs in place of Genevieve M. Zimmerman.

C. Plaintiffs' Steering Committee

[2] Unless otherwise noted Docket Numbers refer to docket entries in the main MDL case. Case Number 08-1943.

Plaintiffs proposed and the Court agreed to the appointment of a Plaintiffs' Steering Committee ("PSC") to assist in the coordination of pretrial activities and trial planning. (*See* Docket No. 977.) The PSC acts on behalf of, or in consultation with, Plaintiffs' Lead Counsel and Liaison Counsel in the management of litigation. Both Plaintiffs' Lead and Liaison Counsel are members of the PSC.[3]

D. Common Benefit Fund

Pretrial Order 3, filed on January 22, 2009, created guidelines for costs and attorneys' fees incurred by PSC members and other attorneys working for the common benefit of Plaintiffs in MDL 1943. (Docket No. 105.) The Order directed Plaintiffs' Liaison Counsel to establish a common benefit fund, provided direction regarding assessments for the common benefit fund, provided the occasions on which disbursements from the common benefit fund are to be made, and set guidelines and deadlines for submission of time and expense costs by Plaintiffs' Counsel.

E. Status Conferences

The initial MDL pretrial conference was held on September 4, 2008. (Docket No. 31.) At the initial conference, the Court set the deadline for filing answers, entered a stipulated confidentiality order, and established docketing and filing procedures. (Docket No. 50.) All discovery disputes and issues during the course of the MDL were handled

[3] The members of the PSC are: Yvonne Flaherty, Lockridge, Grindal Nauen, P.L.L.P, Minneapolis, Minnesota; John P. Walsh, Seattle, Washington; Robert Binstock, Reich & Binstock, Houston, Texas; W. Lewis Garrison, Heninger, Garrison & Davis, Birmingham, Alabama; Troy Giatras, The Giatras Law Firm, Charleston, West Virginia; Brian J. McCormick, Sheller, P.C., Philadelphia, Pennsylvania; and John J. Carey, Carey & Danis, L.L.C., St. Louis, Missouri. (*See* Docket No. 977.)

primarily by the undersigned either through informal telephonic conferences or motion hearings. Periodic status conferences were also held to address status and otherwise time-sensitive issues that arose during the course of the proceedings.

F. Plaintiff Groups

The Court determined that bellwether trials would be useful. For purposes of determining which cases that would be considered for bellwether trials and related case specific discovery, the Court divided the cases into three groups:

> Phase I: The first phase consisted of 15 specifically-identified cases for which case-specific fact discovery was to begin for purposes of selecting cases for bellwether trials. (Docket No. 132.) Subsequently, counsel for the parties narrowed the list to six cases for purposes of selecting cases for bellwether trials. (Docket No. 1036.)
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> Phase II: This group was comprised of thirty-four cases, including nine cases initially included in the 15 Phase I cases and other cases assigned to the MDL in which Defendants had appeared as of December 15, 2008. (Docket Nos. 132, 1036.)
>
> Phase III: This group was comprised of all cases filed in the District of Minnesota or transferred to the MDL not otherwise identified in Phase I or Phase II. (Docket Nos. 132, 1036.)

G. Bellwether Trials

Of the six cases comprising the revised Phase I group, three cases have been tried to verdict: *Schedin v. Ortho-McNeil Pharmaceuticals, Inc.* (Civil Case No. 08-5743); *Christensen v. Johnson & Johnson, et al.* (Civil Case No. 07-3960); and *Straka v. Johnson & Johnson, et al.* (Civil Case No. 08-5742).

1. Schedin v. Ortho-McNeil Pharmaceuticals, Inc.

The first bellwether trial, *Schedin*, was tried in November 2010, and resulted in a jury verdict in favor of Plaintiff against OMJPI[4] in the amount of $700,000 in compensatory damages, which was reduced to $630,000 as a result of the jury's having found Plaintiff 10% negligent. The jury awarded punitive damages in the amount of $1,115,000. Defendant's motion for post-trial relief was denied. Defendant appealed to the Eighth Circuit, which issued a decision on November 30, 2012, affirming this Court's denial of Defendant's motions for judgment as a matter of law or a new trial on Schedin's claim for compensatory damages, and reversing the denial of Defendant's motion for judgment as a matter of law on punitive damages. *See In re Levaquin Prods. Liability Litig.*, 700 F.3d 1161 (8th Cir. 2012). A related appeal was taken from the Court's denial of Defendant's motion pursuant to Federal Rule of Civil Procedure 60 for relief from the judgment. The Eighth Circuit affirmed the Court's denial of Defendant's Rule 60 motion on January 7, 2014. *See In re Levaquin Prods. Liability Litig.*, 739 F.3d 401 (8th Cir. 2014).

2. Christensen v. Johnson & Johnson, et al.

The second bellwether trial, *Christensen*, was tried in June 2011, and resulted in a jury verdict in favor of Defendants Johnson & Johnson and OMJPI.[5] The Court denied Plaintiff's motions for post-trial relief. An appeal was taken, but later was voluntarily dismissed by Plaintiff.

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[4] The other Defendants, Johnson & Johnson and PRD, were voluntarily dismissed prior to trial.

[5] Defendant PRD was voluntarily dismissed prior to trial.

3. Straka v. Johnson & Johnson, et al.

The third bellwether trial, *Straka*, was tried in January 2012, and resulted in a jury verdict in favor of Defendants Johnson & Johnson and Janssen.[6] The Court denied Plaintiff's motions for post-trial relief and no appeal from the Court's order was taken.[7]

DISCOVERY

Pretrial Orders 2, 4 (as amended by Pretrial Order 6), and Pretrial Order 5 govern the pretrial discovery in MDL 1943.

A. Generic Fact Discovery

1. Document Discovery

Plaintiffs have conducted extensive fact discovery against Defendants. Prior to the creation of the MDL, Plaintiffs had propounded initial document requests to Defendants in the individual case *Voss, et al. v. Johnson & Johnson, et al.* (Civil Case No. 06-3728). Defendants produced documents in response to Plaintiffs' requests on a rolling basis.

On August 19, 2009, Plaintiffs served and filed and omnibus motion to compel discovery. On November 25, 2009, the Court granted in part and denied in part Plaintiffs' motion to compel, requiring Defendants to comply with their "continuing obligation to produce documents as they are kept in the usual course of business," provide responses to certain interrogatories, and produce documents related to various

[6] Defendant PRD was voluntarily dismissed prior to trial.

[7] Two cases were also tried as part of consolidated state court proceedings in New Jersey Superior Court, both of which resulted in jury verdicts in favor of Defendants Johnson & Johnson and Janssen in October 2011.

subjects, including documents related to marketing, pricing, sales, revenue, profits and costs, and Levaquin's predecessor drug, Floxin. (Docket No. 732.)

Pursuant to the Federal Rules of Civil Procedure, Defendants prepared and served a privilege log. Plaintiffs challenged certain entries on Defendants' privilege log, and after meeting and conferring with Defendants, Plaintiffs moved to compel production of non-privileged documents. The documents were submitted for *in camera* review by the Court, to Magistrate Judge Arthur J. Boylan, who issued an order on June 30, 2010 granting in part and denying in part Plaintiffs' motion. (Docket No. 1511.)

2. Protective Order/Confidentiality

Prior to the creation of the MDL, the parties in the case of *Voss, et al. v. Johnson & Johnson, et al.* (Civil Case No. 06-3728), had stipulated to the entry of a protective order. (Civil Case No. 06-3728, Docket Nos. 43-44.) The Court incorporated the September 7, 2007 Amended Stipulated Confidentiality Order by reference as part of Pretrial Order 1. (Docket No. 50.)

3. Depositions of Generic Fact Witnesses

The guidelines governing the taking of depositions are outlined in Pretrial Order 2 (Docket No. 70), which includes, in part, a provision for cross-noticing depositions between state court cases and this MDL, and provisions for attendance at depositions, deposition scheduling, document production, and videotaping of depositions.

As part of generic discovery, Plaintiffs deposed approximately twenty-seven current or former employees of Defendants, including Rule 30(b)(6) witnesses either as part of the MDL or through depositions cross-noticed in the New Jersey state court

consolidated matter.[8] Third-party witnesses were also deposed, including John Seeger, Alex Walker, Carla Canabarro, Drew Levy, and Wanju Dai.

B. Case-Specific Fact Discovery

1. Plaintiff Fact Sheets

Pursuant to Pretrial Order 4, the Court directed that each Plaintiff complete a Plaintiff Fact Sheet ("PFS") and serve it on Defendants' Liaison Counsel. The deadlines for service of a PFS are as follows:

Phase I cases: February 15, 2009

Phase II cases: March 16, 2009

Phase III cases: No later than 90 days after Defendants had filed responsive pleadings to the Complaint.[9] (Docket No. 132.)

The PFSs, agreed upon by the parties, included a request that a plaintiff provide information, including but not limited to: the name of the plaintiff, the plaintiff's alleged injuries, the dates upon which Levaquin was prescribed, the warnings, written and verbal instructions plaintiff received about Levaquin, and the plaintiff's employment history, educational history, and medical history. This sworn PFS required each plaintiff to verify

[8] Those witnesses include: Cynthia Chianese, Carl DeStefanis, Daniel Fife, Tiziana Fox, Lorie Gawreluk, Roger Graham, David Grewcock, John Johnson, Larry Johnson, James Kahn, Sara Kennedy, Neil Minton, Gary Noel, Greg Panico, Kim Park, Janet Peterson, Phillip Pierce, Katherine Rielly-Gauvin, Jeffrey Smith, Ira Solomon, Linda Stirano, Robyn Thomas, Teresa Turano, Raymond Werts, Katania Vadana, David Wright, and Chuen Yee.

[9] In Pretrial Order 6, the Court vacated Paragraphs 1 and 2 of Pretrial Order 4 with respect to the cases listed in Phases I and II. Pretrial order 6 provides that the cases listed in Pretrial Order 4 not included in Pretrial Order 6 were to be moved to Phase II. (Docket Nos. 132, 1036.)

the accuracy and completeness of information, and the verifications were given the same legal significance as answers to interrogatories.[10]

2. Defendant Fact Sheets

Pursuant to Pretrial Order 4, Defendants were required to complete and serve a Defendant Fact Sheet ("DFS") in each case as follows:

Phase I cases: 30 days following the receipt of a PFS in each Phase I case

Phase II: 60 days following receipt of a PFS in a Phase II case

Phase III: 90 days following receipt of a PFS in a Phase III case. (Docket Nos. 132, 1036.)

C. Expert Discovery

The parties agreed, and the Court approved, a protocol for the exchange and discovery of information regarding all generic expert witnesses identified in the MDL. Pretrial Order 5 governs the discovery of drafts, communications, and other information from experts; the content of reports; and the applicability of expert depositions to cases in the MDL. (Docket No. 554.)

With respect to expert witnesses for bellwether cases selected for trial, disclosure of the identity of each expert witness and full disclosures as required by Federal Rule of Civil Procedure 26, accompanied by written reports, were to be made for all experts, including generic experts.

GLOBAL ISSUES

[10] A copy of the Plaintiff Fact Sheet form is available on the website for this MDL, located at http://www.mnd.uscourts.gov/MDL-Levaquin/Forms/Levaquin-Plaintiff-Fact-Sheet.pdf.

A. Preemption

Defendants sought dismissal of Plaintiffs' failure to warn claims on the grounds they were preempted under federal law. The Court denied Defendants' motion, ultimately determining that under *Wyeth v. Levine*, 555 U.S. 555 (2009), and *Pliva v. Mensing*, 131 S. Ct. 2567 (2011), Defendants had not proffered evidence that the FDA rejected an actual label change and thus Plaintiffs' claims were not preempted. *See In re Levaquin Prods. Liability Litig.*, MDL No. 08-1943, Civ. No. 08-5742, 2011 WL 6826415, at *5 (D. Minn. Dec. 28, 2011).

B. Punitive Damages

Pursuant to Minnesota law, each Plaintiff in each bellwether trial moved to amend his/her complaint to add a claim for punitive damages. The Court granted each Plaintiff's motion for leave to amend in each case. The Court has not sought to determine the extent to which, if at all, any other state's law relative to punitive damages would apply to any particular plaintiff's claims.

C. *Daubert*

Each side moved to exclude part or all of the testimony of the following generic expert witnesses: Cheryl Blume, Thomas Zizic, Martyn Smith, Gregory Bisson, Martin Wells,[11] Joseph Rodricks, George Zhanel, Paul Waymack, George Holmes, John Seeger, and Peter Layde. The Court issued rulings on these motions.

1. ***Defendants' Motion to Exclude Dr. Blume – Denied*** (Docket No. 2277.)

[11] Plaintiffs brought a motion in limine to exclude the expert testimony of Dr. Martin Wells, but this motion was withdrawn without a ruling from the Court. (Docket No. 1874.)

Defendants sought to exclude Dr. Cheryl Blume's expert testimony on several grounds. First, Defendants argued that Blume lacks the required qualifications to be considered an expert in the field because she is not a medical doctor and has never prescribed Levaquin. They also challenged the legitimacy of her methods and her conclusions. Defendants claimed that the excessive recitation of the factual history of Levaquin in her testimony is an effort to distort the facts, and that such matters should not be the subject of expert testimony.

The Court found that Blume's many years of experience working in the pharmaceutical industry on label changes and interpreting adverse event data qualify her to testify in these proceedings. In addition, the Court found that her methods are well established and accepted, and that any other challenges to the credibility of her testimony can be addressed in cross examination. Finally, the Court determined that Blume must limit her testimony about facts in the case to those sufficient to provide context for the jury. With this exception, the Court denied the motion to exclude Dr. Blume's testimony.

2. Defendants' Motion to Exclude Expert Testimony of Drs. Smith and Zizic – Denied (Docket No. 2260.)

Defendants sought to exclude the expert testimony of Dr. Martyn Smith and Dr. Tom Zizic. Defendants argued that Smith and Zizic's conclusions about the comparative tendon toxicity levels fail to meet the *Daubert* standard of reliable methods, because they rely on extrapolations from animal studies. The Court denied the motion. The Court found that there is no per se rule stating that animal studies are inadmissible as evidence. Rather, this evidence is excluded in cases where there is sufficient reason to question the

legitimacy of extrapolations. Because those issues were not present in this case, the Court found that any question of credibility in the conclusions could be addressed on cross examination.

3. ***Defendants' Motion to Exclude Expert Testimony on the Knowledge, Motives, and Intent of the Defendants – Granted in part and Denied in part*** (Docket No. 2267.)

Defendants moved to exclude testimony by several of Plaintiffs' experts as to the knowledge, motive, and intent of defendants in their participation in levofloxacin studies.[12] Defendants argued that medical experts are not qualified to testify as to the mental processes of the Defendants. Further, Defendants argued that the inferences as to motivations and intentions are factual issues which should be left to the jury to determine. Finally, Defendants contended that any such evidence that would otherwise be admissible should be excluded because it is more prejudicial than probative. The Court granted the motion with respect to statements made concerning particular biases of Defendants. The Court denied the motion as to statements which were made about sources of potential bias generally.[13] The Court found that the statements about particular motivation and intentions of Defendants were unreliable, but that there was nothing objectionable about experts offering general testimony as to possible sources of bias in scientific studies. The Court noted that this type of testimony is routinely allowed by expert witnesses, and admission would not be prejudicial or confusing to a jury.

[12] Specifically, Defendants sought to exclude particular statements by Drs. Zizic, Bisson, and Wells.

[13] The Court excluded two statements by Dr. Wells and one statement by Dr. Bisson.

4. Plaintiffs' Motion to Exclude Expert Testimony of Dr. Rodricks – Denied (Docket No. 3243.)

Plaintiffs moved to exclude Dr. Joseph Rodricks's expert testimony on several specific issues on the grounds that during deposition he stated that he had no opinion on these issues.[14] Additionally Plaintiffs moved to strike his rebuttal report under Federal Rule of Civil Procedure 26(a)(2)(C)(ii), claiming that it offers new opinions not presented in the original report. Plaintiffs further argued that the opinions in the rebuttal report fail to meet the generally accepted standard of *Daubert*. The Court found that Plaintiffs' characterization of Rodricks's testimony and reports was contrary to the record and that the rebuttal did not contain new opinions. The Court further found that Rodricks's report was not excludable under the *Daubert*. The Court denied the motion in its entirety, noting that Plaintiffs could challenge Rodricks' findings on cross-examination.

5. Plaintiffs' Motions to Exclude Expert Testimony of Dr. Zhanel – Denied (Docket No. 2253.)

Plaintiffs sought to exclude Dr. George Zhanel's expert testimony on specific issues because he stated that he had no opinion on those issues, or presented seemingly contradictory opinions on these issues.[15] Upon review of the deposition, the Court found

[14] The particular issues are: 1) any opinion offered in the field of epidemiology; 2) any opinion on the comparative toxicity of ofloxacin and levofloxacin, in animals or humans; 3) Any opinions on whether fluoroquinolones can cause tendon disorder in humans; 4) any opinions on comparative tissue penetration of ofloxacin and levofloxacin, in animals or humans; 5) any opinions on the comparative pharmacokinetics of ofloxacin and levofloxacin; 6) any opinions that there is no reliable animal modeling for studying the comparative tendon toxicity of fluoroquinolones.

[15] The particular issues are: 1) the relative tendon toxicity of various floroquinolones; 2) that a prospective, randomized, double blind clinical trial is the only evidence that can demonstrate a comparative relationship among fluoroquinolones regarding tendon toxicity; 3)

that Zhanel's testimony was consistent, and that his supposed statements about not having an opinion were taken out of context. Consistent with this finding, the Court denied the motion.

6. Plaintiffs' Motions to Exclude Expert Testimony of Dr. Waymack – Granted in part and Denied in Part (Docket No. 3243.)

Plaintiffs sought to exclude Dr. Paul Waymack's expert testimony. Plaintiffs argued that Waymack's testimony concerning FDA regulations is contrary to law, and that coupled with his routine exclusion in previous litigation, his testimony is unreliable. The Court found that much of Waymack's testimony is contrary to the law interpreting current regulations. The Court noted that Waymack's testimony regarding FDA regulations is largely unaltered from previously offered testimony that has been excluded in other cases. The Court also found that this testimony was likely to prejudice or confuse the jury. Pursuant to these findings, the Court granted the motion in part. Waymack was allowed to testify but was not allowed to offer testimony that was contrary to the law as articulated in *Wyeth* and the Court's order. Further, Waymack was not allowed to testify about the specific regulatory history of Levaquin.

7. Plaintiffs' Motions to Exclude Expert Testimony of Dr. Holmes – Denied (Docket No. 3253.)

Plaintiffs sought to exclude the expert testimony of Dr. George Holmes on several grounds. Plaintiffs pointed to several problems with Holmes's testimony which they suggest make his testimony inadmissible: that Holmes is unqualified to testify regarding

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that levofloxacin and ofloxacin have different toxicological and pharmacological profiles; and 4) that levofloxacin is superior to moxifloxacin for upper respiratory illnesses and that levofloxacin is superior to ciprofloxacin for urinary tract infections.

tendon ruptures associated with floraquinolones because he has never prescribed or previously conducted research on the topic; that Holmes's opinions were developed solely for use at this trial; and that Holmes failed to distinguish between *the* and *a* contributing cause and his lack of experience with Levaquin, thereby making a legal argument and not a medical diagnosis. The Court denied the motions, finding that Holmes was well qualified as an expert on the subject. In addition, the Court found no evidence to suggest that Holmes's report or testimony was not properly prepared or that it was inadmissible on the grounds that it was prepared specifically for the litigation. Though the Court denied the motions, it ordered Defendants to advise Holmes that he must use the language "*a* substantial contributing cause" instead of "*the* substantial contributing cause" when testifying about potential causes of tendon rupture.

8. Plaintiffs' Motion to Exclude Expert Testimony of Drs. Seeger & Layde – Denied (Docket No. 3243.)

Plaintiffs sought to exclude the expert testimony of Dr. John Seeger and Dr. Peter Layde on the grounds that their opinions both fail to meet the general acceptance standard of *Daubert*, and are irrelevant because they offer general opinions on issues that are not in dispute. Specifically, Plaintiffs pointed to evidence that the Ingenix study, in which Seeger participated, was improperly conducted and calls into question the legitimacy of the conclusions in his report.[16] Plaintiffs also argued that because Layde's opinions on the associations between injuries and use of medications suggest opinions which he does not purport to have and cannot support with evidence, the testimony is more prejudicial

[16] Defendants did not challenge Dr. Seeger's appearance as a fact witness to discuss the Ingenix study; rather they challenged his appearance solely as an expert.

than probative. The Court denied the motion in its entirety. The Court found that Seeger is qualified to testify as an expert witness. The Court further found that Plaintiffs' complaints about Seeger speak to credibility, not admissibility, and can therefore be addressed on cross-examination. The Court also found that the Rules of Evidence allow experts to testify as to general principles, and since the general principles in Layde's testimony addresses issues pertinent to the case, his testimony was relevant.

D. Other Evidentiary Rulings

The Court also made a number of other general evidentiary rulings that it applied to the bellwether cases as the law of the case.

1. Defendants' Motion to Exclude Foreign Regulatory Actions – Denied (Docket No. 2264.)

Defendants sought to exclude evidence of regulatory documents and proposed regulatory actions for Levaquin from foreign countries. Defendants asserted these documents were not relevant to the claim and should therefore be excluded pursuant to Federal Rule of Evidence 401. Specifically, Defendants argued that in order to get such evidence admitted, the Plaintiffs bear the burden of showing that the treating physician directly relied on the foreign regulations or accompanying documents in arriving at his/her medical decisions. Alternatively, they argued that the evidence was inadmissible as hearsay under Federal Rule of Evidence 803 and would place too onerous a task on the Court in trying to interpret and research the foreign regulation sufficiently under Federal Rule of Civil Procedure 44.1. Finally, Defendants contended that this evidence was unduly prejudicial under Federal Rule of Evidence 403. The Court reasoned that the

evidence was not final regulatory action to which a jury might defer out of confusion: rather, the evidence was preliminary regulatory action and was probative of an intent to limit the impact that regulatory action in Europe might have on the U.S. market. As a result, the Court found the evidence was not hearsay and was admissible. To cure any potential prejudice, the Court issued a limiting instruction.[17]

2. ***Defendants' Motions to Exclude FDA Petitions – Denied*** (Docket No. 2264.)

Defendants sought to exclude evidence of petitions sent to the Food and Drug Administration ("FDA") requesting that the FDA strengthen the warning label on Levaquin.[18] Defendants claimed that the petitions were inadmissible hearsay because no one who could testify as to their production would be called by the defendants. They further argued that, since one of the petitions was drafted before the release of Levaquin and the other was drafted after the Plaintiffs' injuries, they were not relevant to the

[17] The limiting instruction read:

> You have heard evidence on various regulatory issues that occurred outside of the United States. The legal standards used by foreign regulatory agencies may be different from those used in the United States. Therefore, you should not use regulatory actions by foreign regulatory agencies to determine whether or not defendants abided by or violates any legal duty in the United States. However, the evidence surrounding these foreign regulatory events may be considered by you as a basis for understanding defendant's actions in the United States, defendant's notice about issues that were relevant in the United States, and defendant's motives in responding to those issues which may have impact in the United States.

(Civil Case No. 08-5743, Jury Instruction 14, Docket No. 176; Civil Case No. 07-3960, Jury Instruction 14, Docket No. 237.)

[18] The petitions recommended the strengthening of the label on all floraquinolones, not just Levaquin.

specific injury claims. The Defendants also asserted that these petitions are highly prejudicial because they portray the FDA as incapable of effectively regulating the market. The Court denied the motion to exclude since the petitions were relevant and qualified for exemption from the hearsay rules under the public records exception of FRE 803(8). The Court further found arguments that the petitions were overly prejudicial to be without merit.

3. Defendants' Motions to Exclude Adverse Event Reports – Denied (Docket No. 2264.)

Defendants sought to exclude evidence of adverse event reports ("AERs") gathered from two databases.[19] Defendants argued these reports were inadmissible to establish causation because it is widely recognized that AERs are an unreliable method for establishing causation, and the FDA itself refuses to treat such reports as establishing causation; therefore, AERs cannot constitute notice evidence. Defendants further asserted that AERs were irrelevant and hearsay. The Court found the AERs alone might not be permissible as evidence, given their lack of reliability to show a causal link between the plaintiffs' injuries and Levaquin. However, they are commonly used by experts in the field to determine causation in correlation with other evidence. Additionally, even if AERs could not be admitted to prove causation, they constitute notice evidence. The Court found no merit in the hearsay objection so long as the

[19] The AERs at issue are primarily gathered from two databases: one is the FDA's AER database; the other is Sceptre, maintained by the Defendants.

Plaintiffs or Plaintiffs' experts discuss AERs in this context. Therefore, the Court denied the motions. To cure any potential prejudice, the Court issued a limiting instruction.[20]

4. Defendants' Motions to Exclude Evidence of Label Changes Subsequent to Plaintiffs' Injuries – Denied (Docket No. 2326, 3243.)

Defendants sought to exclude evidence of label changes for Levaquin that occurred subsequent to the plaintiffs' prescriptions.[21] Additionally, Defendants moved the Court to exclude evidence of other potential label changes prior to the injury that would have conflicted with current FDA regulations. Defendants argued that label changes after the injury are the product of information that was not available at the time of the prescription and, therefore, were not admissible to show what defendants should have known. Defendants also argued that evidence suggesting that label changes should have been made sooner is inadmissible—particularly an earlier addition of a black box warning—because they were preempted from making these changes by FDA regulations at the time. Further, Defendants emphasized that only the FDA could (and can) mandate

[20] The instruction reads in pertinent part:

> This type of information alone should not be considered by you as evidence of a causal relationship between use of the drug and the injury, but may be considered along with other evidence to determine whether the drug is a substantial contributing factor to the injury. These reports may be considered as one type of evidence of a signal that there may be an association between a drug and the adverse event. Likewise, this type of information or data alone should not be considered by you as evidence of the incidence of the injury associated with the drug, or evidence of making comparisons between drugs. Simply because one drug may have more reports of a particular injury, is not evidence that it presents more of a risk of that injury than other drugs.

(Civil Case No. 08-5743, Jury Instruction 12; Civil Case No. 07-3960, Jury Instruction 12.)

[21] Schedin was prescribed Levaquin in 2005 and Christensen in 2006.

a black box warning, and thus they cannot be held liable for failing to do something they were unable to do.

The Court denied the motion. Specifically, the Court found that even though the decision to institute a black box label was not within the power of Defendants, Defendants could have used other procedural mechanisms to revise and improve the label. The Court also found that the evidence of post-injury label changes was relevant insofar as it demonstrated what the Defendants knew or should have known about the inadequacy of the label at the time of injury. To cure any potential prejudice, the Court issued a limiting instruction.[22]

5. Defendants' Motions to Exclude Evidence of Ortho-McNeil "Ghostwriting" Articles – Denied in part (Docket No. 2264.)

Defendants moved to exclude all evidence and argument that they have "ghostwritten" medical and scientific articles on the appropriate clinical use of Levaquin. While acknowledging the fact that Defendants have, on several occasions, paid third-party vendors to conduct studies and write articles, defendants maintained there is no evidence that they in any way influenced or attempted to influence the outcome of those

[22] The instruction reads in pertinent part:

> You have heard evidence that the FDA approved Levaquin as safe and effective for its intended uses, that the FDA approved Levaquin's label or "package insert" in place at the time of plaintiff's prescription, and that the FDA required changes to the label in 2008 after the time of plaintiff's prescription. . . . . Neither the FDA's approval of the drug and its label, nor its requirement of label changes, is necessarily conclusive or controlling on any issue you have been asked to decide. You may give it as much or as little weight as you think it deserves, in light of all the evidence, under the law as set forth in these instructions.

(Civil Case No. 08-5743, Jury Instruction 13; Civil Case No. 07-3960, Jury Instruction 13.)

studies. On this basis, Defendants contended that the introduction of argument or evidence intimating the contrary would be highly prejudicial. The Court denied these motions, noting that such evidence is routinely admissible in these types of proceedings and relevant in this case. In particular, the Court found that the prescribing physicians relied on the opinions and advice of other experts in the medical community, often the product of relevant medical studies, and they could have contributed to the prescribing physicians' decisions to use Levaquin. The Court therefore denied the motion subject to the exception that Plaintiffs refrain from using the term "ghostwriting," as it is potentially inflammatory and prejudicial.

6. ***Defendants' Motions to Exclude Evidence of Health & Medical Conditions of Persons Other than Plaintiffs – Denied*** (Docket No. 2264.)

Defendants moved the Court to exclude evidence of injuries to persons other than the Plaintiffs. The Court noted that while these motions may have merit, they were not ripe for ruling without knowing the particulars of the injuries, whether they are substantially similar circumstances, or whether they are relevant to an expert's report. The Court therefore denied the motion but left the issue open to appropriate objection during specific proceedings if potentially irrelevant information regarding third parties is raised.

7. ***Defendants' Motions to Exclude Any Reference to Documents Created by Other Pharmaceutical Companies Unrelated to Levofloxacin – Granted*** (Docket No. 2264.)

Defendants sought to exclude evidence of various marketing materials and other documents which are produced by other pharmaceutical companies and are not directly

related to Levofloxacin. The Court granted these motions, reasoning that any evidence of this sort is likely to be irrelevant to the case at hand and could potentially mislead or confuse a jury.

8. ***Cross Motions Regarding Evidence of Defendants' Other Pharmaceutical Products – Evidence Excluded*** (Docket Nos. 2261, 2264.)

Defendants moved to exclude, on the basis of irrelevance and prejudice, evidence of other defective products which have been manufactured and sold by the Defendants. Plaintiffs moved for permission from the Court to introduce the same type of evidence. Plaintiffs argued that such evidence is relevant to counter evidence offered by Defendants of their companies' excellent reputations. The Court excluded the evidence. Taking into account that Defendants had no intention of introducing general evidence of their reputation, the Court determined that the other products failed to be substantially similar to Levaquin and were therefore irrelevant. The Court further noted that allowing such evidence at trial (particularly evidence of product recalls) would waste trial time and be an unnecessary distraction.

9. ***Plaintiffs' Motions to Exclude Evidence on the Rarity of Tendon Rupture – Denied*** (Docket No. 2261.)

Plaintiffs moved to exclude evidence that tendon rupture is a "rare occurrence." The Court denied this motion, finding Defendants could introduce evidence of the statistical rarity of the occurrence.

10. ***Plaintiffs' Motions to Exclude All References to Plaintiff Counsels' Conduct – Denied*** (Docket No. 2261.)

Plaintiffs moved to exclude all reference to Plaintiff counsels' conduct. Specifically, Plaintiffs sought to prevent Defendants from referencing commercials soliciting clients for Levaquin litigation or eliciting testimony suggesting that the Plaintiffs were in any way influenced to sue Defendants by advertisements. Additionally, Plaintiffs sought to exclude any evidence of fee structures or Plaintiff counsels' compensation for the trials. Plaintiffs argued that allowing this type of evidence and testimony would intrude on attorney-client privilege. The Court found that some of the examples given by Plaintiffs' counsel would be protected under attorney-client privilege, but others would not, and denied the motion as overbroad.

11. ***Defendants' Motions to Exclude Evidence of Marketing and Communication for Levaquin to Non-Parties – Denied*** (Docket No. 2264.)

Defendants sought to exclude all evidence of marketing materials or communications about Levaquin which allegedly misrepresented or failed to disclose the risks associated with prescribing the drug. Defendants argued that because there was no evidence that the prescribing physicians ever saw or relied on statements in these marketing materials, they are irrelevant and inadmissible. The Court found that these materials may have shaped the way that marketing and sales representatives represented Levaquin to physicians in general, and thus may have indirectly influenced the prescribing physicians. The Court denied this motion.

12. ***Plaintiffs' Motions to Exclude Evidence that Plaintiffs' Injuries May Have Been the Result of Other Defective Products – Denied*** (Docket No. 2261.)

Plaintiffs sought to exclude any mention, suggestion, or attempt to elicit testimony that Plaintiffs' injuries were caused by another defective product. Plaintiffs argued that there is no expert designated to substantiate such a claim, and that this would amount to an affirmative defense that Defendants waived. Therefore, Plaintiffs argued, the introduction of such evidence would be overly prejudicial, and likely to confuse or mislead the jury. Defendants maintained that they only waived the defense of superseding cause, and never intended to waive a defense of alternative causation. The Court denied the motion because the possibility of alternative causation is relevant.

ACTIONS COMPLETED BEFORE REMAND

The cases listed in Exhibit A are ripe for remand. They are cases in which Plaintiffs have completed generic discovery of Defendants. The plaintiff in each case has served a PFS, and Defendants have served a DFS. The cases have not been settled. Furthermore, the Court has instituted procedures, through the use of various types of orders to show cause, to ensure that the cases listed in Exhibit A are cases in which Plaintiffs have recently indicated their desire to move forward with their cases.

These cases will require case-specific depositions of the plaintiff, treating physician(s), case-specific expert designations, and pretrial motions, all of which can be addressed by the transferor courts. Certain other case-specific issues are addressed below.

CASE-SPECIFIC ISSUES FOR RESOLUTION

A. Damage Caps, Other Limitations on Recovery, and State Consumer Fraud Statutes

Because all of the bellwether trials involved cases brought by Minnesota residents and involved cases originally filed in the District of Minnesota, the Court has not sought to determine, and has not addressed, whether and/or to what extent statutory damage caps or other limitations on recovery existing under other state statutes may apply to any particular plaintiff's claims for those cases listed in Exhibit A.

Further, this Court has not sought to determine, and has not addressed, whether and/or to what extent any claim of a violation of any other state's statutory consumer fraud laws by any plaintiff listed in Exhibit A has merit.

B. Statutes of Limitations

Because case-specific discovery has been limited in the MDL, and because variability exists among state laws as to when an applicable limitation period began to run, issues as to whether a particular plaintiff's claim in any of the cases listed in Exhibit A are barred by an applicable statute of limitations have not been submitted to this Court for determination. The Court anticipates that in certain cases, the transferor courts may be required to evaluate whether a particular plaintiff has timely filed his/her claims.

C. *Daubert*

In light of medical and legal causation challenges addressed by the Court in each of the bellwether trial cases, this Court anticipates that transferor courts will likely need to address *Daubert* challenges to case-specific medical experts.[23]

[23] In the consolidated state court proceedings in New Jersey, the court addressed the adequacy of the Levaquin black box warning that was mandated by the FDA beginning in July 2008, holding that the warning was adequate as a matter of law. *Hain et al. v. Johnson & Johnson, et. al*, Court File No. ATL-L-8568-11-MT (Higbee, J. June 13, 2013).

DOCUMENTS TO BE SENT TO TRANSFEROR COURTS

After receiving the Final Remand Order ("FRO") from the JPML, the Clerk of Court will issue a letter to the transferor courts, via email, setting out the process for transferring the individual cases listed in the FRO. The letter and certified copy of the FRO will be sent to the transferor court's email address.

If a party believes that the Docket Sheet for a particular case to be remanded is not correct, a party to that case may, with notice to all other parties in the case, file with the transferor court a Designation Amending the Record. Upon receiving a Designation Amending the Record, the transferor court may make any needed changes to the docket. If the docket is revised to include additional documents, the parties should provide those documents to the transferor court.

OBJECTIONS TO REMAND

If a plaintiff identified in Exhibit A believes his/her case should not be remanded, he/she shall file a Notice of Objection to this Final Pretrial Order and Suggestion of Remand within thirty (30) days of the entry of this Order, including in his or her Notice a basis for objection.

DATED: September 10, 2014
at Minneapolis, Minnesota.

s/John R. Tunheim
JOHN R. TUNHEIM
United States District Judge

EXHIBIT A
Cases Subject to Order

Count	Plaintiff Name	Case Number	Plaintiff's Counsel
1	Bailey, Gwendolyn	MDL: 10-3051 Orig: N.D. Ga. 10-01415	Lanham & McGehee
2	Bennett, Bambi	MDL: 09-3643 Orig: E.D. Mo. 09-01639	Gray Ritter & Graham
3	Bouse, Donna and Frank	MDL: 11-1715 Orig: E.D.N.Y. 2:11- 02236	Soffey & Soffey
4	Bouse, Wendy and Cornell	MDL: 11-2286 Orig: E.D.N.Y. 2:11- 03551	Soffey & Soffey
5	Burke, Tess and Tommy	MDL: 09-3642 Orig: W.D. Ark. 09-04124	Provost Umphrey
6	Campora, Donna, *for the Estate of Mario Campora, deceased*	MDL: 11-2731 Orig: D. Mass. 3:11- 30221	Ross & Ross
7	Dement, Arthur	MDL: 12-0043 Orig: C.D. Cal. 11-10498	Girardi & Keese
8	Dewey, David	MDL: 12-2276 Orig: D.N.M. 12-00785	Steve K. Sanders & Associates
9	Edwards, Sharon	MDL: 12-2654 Orig: E.D.N.Y. 2:12- 04754	Girardi & Keese
10	Ellinghausen, Lynn and Dale	MDL: 11-3719 Orig: N.D. Ala. 11-04095	Sheller, PC
11	Fagler, Willard C. and Rosemary	MDL: 13-0564 Orig: N.D. Fla. 13-00028	Fisher Butts Sechrest & Warner PA
12	Fredrich, Laurie	MDL: 10-4698 Orig: D. Nev. 10-01796	Jones Vargas

Count	Plaintiff Name	Case Number	Plaintiff's Counsel
13	Frenger, Richard	MDL: 12-2653 Orig: E.D.N.Y. 2:12- 04753	Girardi & Keese
14	Gibson, Charles E., III	MDL: 10-03818 Orig: S.D. Miss. 3:10-00385	Hawkins, Stracener & Gibson
15	Greenfield, Stewart	MDL: 11-2997 Orig: D. Conn. 11-01476	Stratton Faxon
16	Hammond, Patricia *as personal representative of Richard Hammond deceased*	MDL: 08-4698 Orig: W.D. Wash. 07-01876	Law Office of John P. Walsh
17	Handley, Mark	MDL: 12-2737 Orig: C.D. Cal. 2:12- 08352	Girardi & Keese
18	Hedrick, Heidi	MDL: 10-3815 Orig: D. Colo. 10-00893	Hillyard, Wahlberg, Kudla & Sloane
19	Henry-Samuel, Christelle	MDL: 12-2741 Orig: S.D.N.Y. 1:12- 07320	Girardi & Keese
20	Hostetler, Max and Diane	MDL: 11-3065 Orig: N.D. Ind. 11-00313	Padove Law
21	Hurst, Harold Ray	MDL: 10-3903 Orig: N.D. Fla. 10-00308	Sidney L. Matthew
22	Jackson, Sallie Tomlinson	MDL: 10-4559 Orig: D.S.C. 10-02650	The Allen Law Firm
23	Johnston, Paula and Marty	MDL: 10-0475 Orig: S.D. Miss. 10-00031	Gilmer Law Firm
24	Kamp, Derek	MDL: 10-4043 Orig: N.D. Tex. 10-1543	The Schiller Firm
25	Lankford, David	MDL: 10-0993 Orig: E.D. Okla. 10-00051	Edwards Law Office

Count	Plaintiff Name	Case Number	Plaintiff's Counsel
26	Larson, Andrew and Roxanne	MDL: 10-4878 Orig: D. Mont. 10-00061	Knight, Dahood, Everett & Sievers
27	Lindsay, Lori	MDL: 12-1159 Orig: D. Conn. 12-00642	Stratton Faxon
28	Litton, Earl	MDL: 09-3644 Orig: N.D. Miss. 09-00104	Kobs & Philley
29	Llorente, Kristen	MDL: 12-2738 Orig: C.D. Cal. 8:12- 01646	Girardi & Keese
30	Majetic, Michael	MDL: 11-3339 Orig: N.D. Ill. 11-07305	Romanucci & Blandin
31	Marlar, Michael	MDL: 10-4697 Orig: D. Neb. 10-03204	Knudsen Berkheimer Richardson & Endacott
32	McCullough, Richard	MDL: 11-3455 Orig: D. Colo. 11-02525	Hillyard, Wahlberg, Kudla & Sloane
33	Meyer, Janice	MDL: 12-2652 Orig: E.D.N.Y. 2:12- 04752	Girardi & Keese
34	Mills, John	MDL: 11-1644 Orig: W.D. Okla.	Delluomo & Crow
35	Nicholas, Kristin	MDL: 11-2085 Orig: C.D. Cal. 11-05761	Brian C. Gonzalez Law Offices
36	Person, Victor	MDL: 11-1181 Orig: C.D. Cal.	Girardi & Keese
37	Presley, Lisa	MDL: 10-3821 Orig: E.D. Tex. 10-00200	Provost Umphrey
38	Ramsey, Wilson "Bill" Jr.	MDL: 10-00995 Orig: E.D. Tex. 09-00564	Law Firm of Barrett W. Stetson

Count	Plaintiff Name	Case Number	Plaintiff's Counsel
39	Randle, Carolyn L.	MDL: 10-3910 Orig: D.N.J. 10-03515	Sheller, PC
40	Rosenberg, Eric	MDL: 09-2887 Orig: S.D.N.Y. 1:09-07753	Law Office of Joseph Lichtenstein
41	Ruttenberg, Emil	MDL: 12-2736 Orig: C.D. Cal. 10-01929	Girardi & Keese
42	Sandifer, George	MDL: 11-2179 Orig: S.D. Miss. 11-00443	Gilmer Law Firm
43	Sandifer, Robert G.	MDL: 11-2181 Orig: S.D. Miss. 11-00445	Gilmer Law Firm
44	Schriner, Bonnie	MDL: 10-1915 Orig: D. Colo. 10-00315	Hillyard, Wahlberg, Kudla & Sloane
45	Semos, Mark	MDL: 10-1906 Orig: C.D. Cal. 10-01929	Girardi & Keese
46	Smith, Amanda	MDL: 13-1489 Orig: D. Kan. 13-04060	Law Office of Dennis Hawver
47	Stanley, Debra C. and Wrenn W.	MDL: 11-2180 Orig: S.D. Miss. 11-00444	Gilmer Law Firm
48	Sussman, Jerrold and Eileen	MDL: 10-3909 Orig: D.N.J. 10-03514	Sheller, PC
49	Sylvester, Susan	MDL: 09-3091 Orig: E.D.N.Y. 09-03075	Richard J. Jaegers
50	Teague, Joan	MDL: 12-2735 Orig: D of Az. 2:12- 02005	Girardi & Keese
51	Thaxton, Michael	MDL: 10-0471 Orig: N.D. Fla. 09-00463	Sidney L. Matthew

Count	Plaintiff Name	Case Number	Plaintiff's Counsel
52	Trask, Lee and Bergstein, Scotty	MDL: 09-2218 Orig: C.D. Cal. 09-04897	Henderson Humphrey
53	Urynowicz, Barbara	MDL: 11-2937 Orig: D. Colo. 11-01703	Hillyard, Wahlberg, Kudla & Sloane
54	Watsky, Marvin	MDL: 12-2740 Orig: E.D.N.Y. 1:12- 04755	Girardi & Keese
55	West, Kathrin Jeannie	MDL: 12-2739 Orig: C.D. Cal. 8:12- 01657	Girardi & Keese
56	Wickerd, Mark	MDL: 13-0148 Orig: D. Conn. 12-01268	Duggan & Caccavaro